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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,186	03/23/2004	Milan Graovac	13180-30	2024

1059 7590 07/11/2006

BERESKIN AND PARR
40 KING STREET WEST
BOX 401
TORONTO, ON M5H 3Y2
CANADA

EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,186	GRAOVAC ET AL.	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1, drawn to claims 1-21, in the reply filed on 06/01/2006 is acknowledged.

2. Claims 22-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/01/2006.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

4. The information disclosure statement(s) (IDS) submitted on 07/27/2004 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

5. Regarding the non-patent literature documents, the examiner notes that (a) the Clay et al document was submitted twice and (b) the Woo et al document is not present.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 and 7-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Shmulewitz et al (US 6,095,987). Shmulewitz et al discloses disease diagnosing bioimpedance analysis methods, comprising:

- (a) representing a body part; as *i* numbers of "compartments" as in Equation (2) in column 6, with a grid having a plurality of finite elements (column 6 line 30 – column 7 line 9);
- (b) obtaining a set of weights, W_i as in Equation (2) in column 6, associated with a particular one of the plurality of finite elements using a model of the body part (column 6 line 30 – column 7 line 9);
- (c) computing a diagnostic, I(t) as in Equation (2) in column 6, at the particular finite element, the diagnostic being a function of the set of weights, and a measured electrical property obtained with an electrode array (column 5 lines 43-65); and
- (d) utilizing the diagnostic (column 16 line 23 – column 17 line 26) to diagnose the possibility of disease in the body part.

8. For claims 2-4 and 7-9, Shmulewitz et al discloses disease diagnosing bioimpedance analysis methods, further comprising: obtaining a baseline electrical

property, a conditioned impedance value (column 7 lines 46-63), associated with the body part using a model, a control subject, or a finite element method (column 6 lines 50-64) thereof, wherein the diagnostic, I(t) as in Equation (2) in column 6, is a function of the baseline electrical property, the set of weights, and the measured electrical property obtained with the electrode array.

9. For claims 10-11, Shmulewitz et al discloses disease diagnosing bioimpedance analysis methods, wherein the baseline electrical property (column 7 lines 46-63) is obtained assuming non-uniform resistivity (column 4 lines 24-36) by obtaining a baseline voltage and using the baseline voltage to compute a baseline impedance (column 8 lines 57-67).

10. For claims 12-14, Shmulewitz et al discloses disease diagnosing bioimpedance analysis methods, further comprising:

- (e) applying a plurality of electrodes to the body part (column 5 lines 44-66);
- (f) obtaining a measured electrical property of the body part with the plurality of electrodes (column 5 lines 44-66);
- (g) wherein the step of applying includes applying current through each set of current injection electrode pairs on the body part and applying voltage measurement through each set of electrode pairs on the body part, wherein each of the current injection electrode pairs is associated with one of voltage measurement electrode pairs (column 5 lines 44-66 and column 8 line 57 – column 9 line 16); and
- (h) wherein said step (g) further comprises starting the current injection process with one first pair of injecting electrodes and applying voltage measurement through one

first pair of voltage measuring electrodes and repeating this process through *i* numbers of electrode pairs to obtain a measured impedance (column 5 lines 44-66 and column 8 line 57 – column 9 line 16).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 5-6 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shmulewitz et al in view of Clay et al (IDS Non-Patent Literature, Cite 1: IEEE Transactions on Medical Imaging, Vol. 21, No. 6, June 2002).

14. For claims 5-6, Shmulewitz et al discloses the claimed disease diagnosing bioimpedance analysis methods except for explicitly disclosing in the step of

representing, (a), the grid is a two- or three- dimensional. Clay et al teaches disease diagnosing bioimpedance analysis methods including representing a body part with a grid having a plurality of finite elements in either two or three dimensions (page 630 Part II.B. and page 636 Part IV.). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the impedance based diagnostic method as taught by Shmulewitz et al, with dimensional considerations as taught by Clay et al for the purpose of increasing the efficacy of diagnosing disease based upon electrical measurements taken on a body.

15. For claims 15-21, Shmulewitz et al discloses the claimed disease diagnosing bioimpedance analysis methods as aforementioned, including: (a) weighting measured and calculated electrical parameters associated with electrode pairs and (b) using the body part model to obtain a set of baseline impedances associated with electrode pairs, except for explicitly disclosing: (a) using the body part model to obtain a set of current densities, (b) calculating an average of the diagnostic function both as a global average and as an average of the diagnostic computed at each finite element, (c) calculating a second averaged diagnostic correlated to a homologous body part, (d) expressing the diagnostic function in terms of an individual finite element as a calculated individual impedance divided by the measured individual impedance, and (e) calculating the difference or difference divided by the averaged diagnostics between first and second averaged diagnostics to indicate the possibility of disease in the body part or homologous body part.

16. Clay et teaches disease diagnosing bioimpedance analysis methods including (a) using the body part model to obtain a set of current densities (page 630 parts II.A. and II.C.), (b) calculating an average of the diagnostic function both as a global average and as an average of the diagnostic computed at each finite element (page 631 equation 8), (c) calculating a second averaged diagnostic correlated to a homologous body part (page 634 part D and Figure 3), (d) expressing the diagnostic function in terms of an individual finite element as a calculated individual impedance divided by the measured individual impedance via weighting (page 632 equation 18), and (e) calculating the difference or difference divided by the averaged diagnostics between first and second averaged diagnostics (Tables I-IV) to indicate the possibility of disease in the body part or homologous body part.

17. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the impedance based diagnostic method as taught by Shmulewitz et al, with the teachings of Clay et al for the purpose of increasing the efficacy of diagnosing disease based upon electrical measurements taken on a body and standard finite element modeling mathematics.

Conclusion

18. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Church et al (US 6,501,984 B1), Gregory (US 6,522,910 B1), and Isaacson et al (US 5,588,429) each disclose processes for producing optimal diagnostics based upon calculated and measured electrical values.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JGH

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700